



PATENT  
Customer No. 22,852  
Attorney Docket No. 03715.0123-02  
(Formerly 03806.0449-02)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
 )  
 Michel BUREAU et al. ) Group Art Unit: 1632  
 )  
 Application No.: 09/986,033 ) Examiner: Joseph T. Weitach  
 )  
 Filed: November 7, 2001 )  
 )  
 For: A METHOD FOR )  
 TRANSFERRING NUCLEIC ACID )  
 INTO STRIATED MUSCLES )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Office the documents listed on the attached PTO 1449 form. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a final action, Quayle action, or a notice of allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed documents are attached. Applicants respectfully request that the Office consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

03/24/2004 CCHW1 00000004 09986033

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The relevancy of European applications EP 0 259 212 B1 and EP 0 140 308 B2 may be found in the attached English-language abstracts.

French application FR 2 688 514 is related to WO 93/19191, while French application FR 2 681 786 is related to WO 93/06223. The relevancy of the two French applications may be found in the English-language abstracts of the corresponding PCT applications. (See the first page of each PCT application.)

Finally, the relevancy of WO 97/10343 may be found in its English-language abstract.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Office applies any of the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

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If there is any fee due in connection with the filing of this Statement that is not found herewith, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

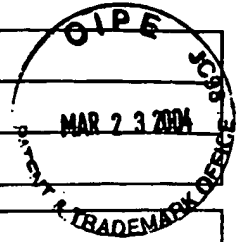
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: March 23, 2004

By: Elizabeth A. Doherty  
Elizabeth A. Doherty  
Reg. No. 50,894

## INFORMATION DISCLOSURE CITATION

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## U.S. PATENT DOCUMENTS

Examiner Initial*		Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
gu	A	6,696,420 B1	2/24/2004	Perricaudet et al.	514	44	
	B	6,426,216 B1	6/30/2002	Perricaudet et al.	435	320.1	
	C	6,007,806	12/28/1999	Lathe et al.	424	93.2	
	D	5,744,133	4/28/1998	Lathe et al.	424	93.2	
	E	6,678,556 B1	1/13/2004	Nolan et al.	604	21	

## FOREIGN PATENT DOCUMENTS

Examiner Initial*		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
gu	F	EP 0 321 201 B1	6/21/1989	EPO	C 12 N	9/00	
	G	EP 0 185 573 B1	6/25/1986	EPO	C 12 N	15/36	English Abstract
	H	EP 0 259 212 B1	3/9/1988	EPO	C 12 N	15/00	English Abstract
	I	EP 0 140 308 B2	5/8/1985	EPO	C 12 N	15/11	

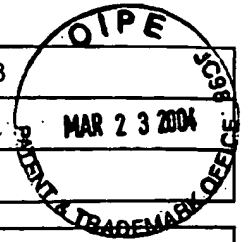
## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

gu	1	J.-P. Behr et al. "Efficient Gene Transfer into Mammalian Primary Endocrine Cells with Lipopolyamine-coated DNA," <i>Proc. Natl. Acad. Sci. USA</i> 86:6982-6986 (1989).
	2	O. Boussif et al. "A Versatile Vector for Gene and Oligonucleotide Transfer into Cells in Culture and <i>in Vivo</i> : Polyethylenimine," <i>Proc. Natl. Acad. Sci. USA</i> 92:7297-7301 (1995).
	3	I. Danko et al. "Pharmacological Enhancement of <i>in Vivo</i> Foreign Gene Expression in Muscle," <i>Gene Therapy</i> 1:114-121 (1994).
	4	H.L. Davis et al. "Direct Gene Transfer into Skeletal Muscle <i>in Vivo</i> : Factors Affecting Efficiency of Transfer and Stability of Expression," <i>Human Gene Therapy</i> 4:151-159 (1993).
	5	H.L. Davis et al. "DNA Vaccine for Hepatitis B: Evidence for Immunogenicity in Chimpanzees and Comparison with Other Vaccines," <i>Proc. Natl. Acad. Sci. USA</i> 93:7213-7218 (1996).
	6	P.L. Felgner et al. "Lipofection: A Highly Efficient, Lipid-Mediated DNA-transfection Procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417 (1987).

Examiner		Date Considered	2/17/05
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
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aw	J	FR 2 688 514	9/17/1993	France	C 12 N	15/87	No
	K	FR 2 681 786	4/2/1993	France	A 61 K	31/70	No
	L	WO 93/19191 A1	9/30/1993	PCT	C 12 N	15/86	English Abstract
	M	WO 93/06223	4/1/1993	PCT	C 12 N	15/86	English Abstract
	N	WO 96/01414	1/18/1996	PCT	G 01 L	13/02	
	O	WO 97/10343	3/20/1997	PCT	C 12 N	15/69	English Abstract

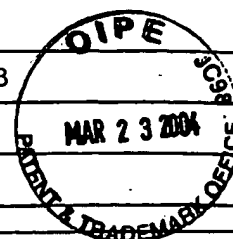
## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

76	7	J. Jouanneau et al. "Secretred or Nonsecreted Forms of Acidic Fibroblast Growth Factor Produced by Transfected Epithelial Cells Influence Cell Morphology, Motility, and Invasive Potential," <i>Proc. Natl. Acad. Sci. USA</i> 88:2893-2897 (1991).
	8	M. Manthorpe et al. "Gene Therapy by Intramuscular Injetion of Plasmid DNA: Studies on Firefly Luciferase Gene Expression in Mice," <i>Human Gene Therapy</i> 4:419-431 (1993).
	9	L.M Mir et al. "Electrochemotherapy Potentiation of Antitumour Effect of Bleomycin by Local Electric Pulses," <i>Eur. J. Cancer</i> 27(1):68-72 (1991).
	10	R.J. Mumper et al. "Polyvinyl Derivatives as Novel Interactive Polymers for Controlled Gene Delivery to Muscle," <i>Pharmaceutical Research</i> 13(5):701-709 (1996).
	11	P. Nouvel et al. "The Spread of a Replication-Competent MuLV Retroviral Vector can be Efficiently Blocked by Deletion Variants" <i>Virology</i> 204:180-189 (1994).
	12	R.S. Williams et al. "Introduction of Foreign Genes into Tissues of Living Mice by DNA-Coated Microprojectiles," <i>Proc. Natl. Acad. Sci. USA</i> 88:2726-2730 (1991).
	13	B. Schwartz et al. "Gene Transfer by Naked DNA into Adult Mouse Brain," <i>Gene Therapy</i> 3:405-411 (1996).
	14	M. Vitadello et al. "Gene Transfer in Regenerating Muscle," <i>Human Gene Therapy</i> 5:11-18 (1994).
	15	P. Wils et al. "Efficient Purification of Plasmid DNA for Gene Transfer Using Triple-Helix Affinity Chromatography," <i>Gene Therapy</i> 4:323-330 (1997).
	16	J.A. Wolff et al. "Direct Gene Transfer into Mouse Muscle <i>in Vitro</i> ," <i>Science</i> 247:1465-1468 (1990).

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

76	17	J.A. Wolff et al. "Conditions Affecting Direct Gene Transfer into Rodent Muscle <i>in Vivo</i> ," <i>BioTechniques</i> 11(4):474-485 (1991).
	18	N. Saidenberg-Kermanac'h et al. "Efficacy of Interleukin-10 Gene Electrotransfer into Skeletal Muscle in Mice with Collagen-Induced Arthritis," <i>J. Gene Med.</i> 5:164-171 (2003).
	19	V. Deleuze et al. "LPS-induced Bronchial Hyperreactivity: Interference by mL-10 Differs According to Site of Delivery," <i>Am. J. Physiol. Lung Cell Mol. Physiol.</i> 286:L98-L105 (2004).
	20	P.-F. Pradat et al. "Viral and Non-viral Gene Therapy Partially Prevents Experimental Cisplatin-induced Neuropathy," <i>Gene Therapy</i> 9:1333-1337 (2002).
	21	M.F. Bureau and D. Scherman "Plasmid DNA Electrotransfer: A New Non Viral Method for Gene Therapy in Oncology," <i>Technology in Cancer Research and Treatment</i> 1(2):149-152 (2002).
	22	J.T. Vilquin et al. "Electrotransfer of Naked DNA in the Skeletal Muscles of Animal Models of Muscular Dystrophies," <i>Gene Therapy</i> 8:1097-1107 (2001).
	23	H. Gollins et al. "High-efficiency Plasmid Gene Transfer into Dystrophic Muscle," <i>Gene Therapy</i> 10:504-512 (2003).
	24	E. Payen et al. "Improvement of Mouse $\beta$ -thalassemia by Electrotransfer of Erythropoietin cDNA," <i>Experimental Hematology</i> 29:295-300 (2001).
	25	M. Faria et al. "Phosphoramidate Oligonucleotides as Potent Antisense Molecules in Cells and <i>in vivo</i> ," <i>Nature Biotechnology</i> 19:40-44 (2001).
	26	M. Bachy et al. "Electric Pulses Increase the Immunogenicity of an Influenza DNA Vaccine Injected Intramuscularly in the Mouse," <i>Vaccine</i> 19:1688-1693 (2001).
	27	J.-S. Silvestre et al. "Antiangiogenic Effect of Interleukin-10 in Ischemia-Induced Angiogenesis in Mice Hindlimb," <i>Circulation Research</i> 87:448-452 (2000).
	28	M. Bettan et al. "High-Level Protein Secretion into Blood Circulation after Electric Pulse-Mediated Gene Transfer into Skeletal Muscle," <i>Molecular Therapy</i> 2(3):204-210 (2000).
	29	P. Kreiss et al. "Erythropoietin Secretion and Physiological Effect in Mouse After Intramuscular Plasmid DNA Electrotransfer," <i>J. Gene Med.</i> 1:245-250 (1999).
	30	M.F. Bureau et al. "Intramuscular Plasmid DNA Electrotransfer Biodistribution and Degradation," <i>Biochimica et Biophysica Acta</i> 1676:138-148 (2004).
	31	P. Bigey et al. "In vivo Plasmid DNA Electrotransfer," <i>Current Opinion in Biotechnology</i> 13:443-447 (2002).
	32	D. Scherman et al. "Applications of Plasmid Electrotransfer," <i>Technology in Cancer Research and Treatment</i> 1(5):351-354 (2002).

Examiner	<i>John W. [Signature]</i>	Date Considered	2/17/05
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